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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,822	10/24/2005	Mark Brister	PA1187	3938
28390 7590 01/14/2010 MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403				
EXAMINER HOUSTON, ELIZABETH				
ART UNIT		PAPER NUMBER		
3731				
NOTIFICATION DATE		DELIVERY MODE		
01/14/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

### Office Action Summary

**Application No.**

10/531,822

**Applicant(s)**

BRISTER, MARK

**Examiner**

ELIZABETH HOUSTON

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 and 8-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

1. Claims 1 and 6 are objected to because of the following informalities: Claims 1 and 6 recite "the first coating *section* is disposed on and completely covers the outer surface" and "the second coating *section* is disposed on and completely covers the outer surface". Stating that a *section* is disposed on a portion of the stent is awkward. Applicant is respectfully asked to verify whether this was applicant's intention or not. With respect to the other claims, examiner believes it more appropriate to recite --- *the first coating is disposed on* ----. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1, 3-6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al (US 6,616,765).**

3. Regarding claims 1 and 6, Castro discloses the invention substantially as claimed comprising a catheter, a balloon operably attached to the catheter, and a stent disposed on the balloon (col. 1, lines 19-27). The stent has a plurality of end to end

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longitudinally adjacent cylindrical stent segments (See Fig. 6a), the axis of the stent segments lying along a longitudinal axis. The stent has a first and second region continuous over at least one pair of adjacent cylindrical segments (see below). A first and second coating including a first coating section and a second coating section respectively with first and second polymers (10; 80) respectively that are disposed on and completely cover the outer surface of the longitudinally adjacent cylindrical stent segments in the first and second regions respectively. The first region and second region are discrete, and the first coating section and second coating section are discrete (See marked up figures below where the first figure is the stent as a whole (Fig. 6a) denoting the cylindrical sections or rings of the stent and the second figure is stent formation put together to show how a stent would appear with the coating arrangement depicted in Fig. 14b. Note that each coating in and of itself delineates its own coating section. Note that the claim does not distinguish that only one coating can exist in the either of the regions).



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4. Regarding claims 3, 4, 8, and 9, Castro discloses that the first coating section includes a first therapeutic agent and that the second coating section includes a second therapeutic agent (col. 17, line 64 – col. 18, line 2).
5. Regarding claims 5 and 10, Castro discloses that the first and second regions can form a striped, spotted or ring pattern (see above depicting a striped pattern and note that the choosing of regions is subjective and not limited by the claims).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765).**
8. Regarding claim 22, Castro discloses a stent having a plurality of cylindrical segments (78) having a first discrete region and a second discrete region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments (see figures above), a first polymer including a first therapeutic agent (10), the first polymer disposed on and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments (78) as a first coating section of a coating, and a second polymer including a second therapeutic agent (80), the second

polymer disposed on and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments (78) as a second coating section of the coating (see figures above; col. 17, line 60 – col. 18, line 3). Castro does not explicitly disclose that the first region has a longitudinal length greater than the diameter of the stent in an expanded stent. However, it would be obvious to vary the length of the stent and the diameter of the stent to result in a stent where the length is greater than the diameter. It is well known in the art that the length and diameter will need to be varied depending on where the stent is intended to be delivered. Since the region can extend the length of the stent, and the length can be modified to be greater than the diameter of the stent, the modified Castro would meet this limitation. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

9. Regarding claim 23, Castro further discloses that the first and second discrete regions are separated by a bare section (see above).

10. Regarding claims 24 and 25, Castro discloses the invention substantially as claimed above except for exact dimensions. However, as shown in the figures above, the location of the first and second regions and thus the dimensions of the bare section are variable. Additionally, the dimension of the bare section will change depending on whether the stent is expanded or compressed. Thus, it would have been obvious to vary the locations of the regions to meet the limitations of the claim. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

11. Regarding claims 11 and 18, Castro discloses the invention substantially as claimed above, further disclosing mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (col. 11, lines 7-13), applying the first polymer solution to the first region to form a first coating section of a coating completely covering the outer surface of the longitudinal adjacent cylindrical stent segments in the first region (col. 14, lines 65-67), mixing a second polymer and second therapeutic agent with a solvent to form a second polymer solution (col. 17, line 62 – col. 18, line 4), and applying the second polymer solution to the second region to form a second coating section of the coating completely covering the outer surface of the longitudinal adjacent cylindrical stent segments in the second region (col. 18, lines 14-32). Castro does not explicitly disclose that the first region has a longitudinal length greater than the diameter of the stent in an expanded stent. However, it would be obvious to vary the length of the stent and the diameter of the stent to result in a stent where the length is greater than the diameter. It is well known in the art that the length and diameter will need to be varied depending on where the stent is intended to be delivered. Since the region can extend the length of the stent, and the length can be modified to be greater than the diameter of the stent, the modified Castro would meet this limitation.

12. Castro fails to specifically disclose that the solvent mixed with the second polymer and second therapeutic agent is a second solvent, but teaches that it could be a second solvent (col. 11, lines 55-59; col. 12, lines 20-24). Choosing a solvent based on the polymer chosen implies that if a second polymer is used, then a second solvent will also be used. Further, Castro discloses that all other variables of the second



composition are different than that of the first, so it would have been obvious to choose a second solvent when forming the second polymer solution. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

13. Regarding claims 12 and 19, Castro further discloses the first and second polymer solutions may be applied simultaneously (col. 17, lines 61-64). Regarding claims 13 and 20, Castro discloses curing the first and second polymer solutions (col. 9, lines 64-65). Regarding claims 14 and 21, Castro further discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (col. 6, lines 24-35). Regarding claims 15-17, Castro further discloses mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).

### ***Response to Arguments***

14. Applicant's arguments filed 10/27/09 have been fully considered but they are not persuasive. Applicant argues that "stent segment as claimed and described in the specification" refers to the segments forming the stent such as W-shaped segments 160. Applicant refers to Castro C14:L58-61 as referring only to strut 68 in figure 6a. While Castor does not specifically point out the stent is made of cylindrical stent segments lined up end to end along the longitudinal axis, one of skill in the art would clearly be able to discern from Figure 6a that Castro's stent does in fact include

cylindrical stent segments in the same way that is described in the instant disclosure. For sake of argument, examiner has supplied a marked up figure that depicting the interpretation of the cylindrical stent segments that should be apparent from cursory review of the figure.

### ***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

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